DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

August 4, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ms. Gloria Donaldson, President
Donaldson & Hasenbein
dba J & R Feed Service, Inc.
100 8th Street N.E.
Cullman, AL 35055

Warning Letter No. 03-NSV-23

Dear Ms. Donaldson:

An inspection of your medicated feed mill on April 15-16, 2003 by a Food and Drug Administration investigator found significant deviations from the Current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR) Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection found:

- failure to properly handle drugs in the mixing area, as indicated by the two bags of expired drug found in the active drug storage area and in the use of a common weighing bucket. The expired drugs compromised drug integrity, as the manufacturers guarantee drug potency through the expiration date, but not beyond. In addition, your use of the same bucket to weigh-up different drugs without cleaning the bucket exposes the drugs to cross-contamination. Such handling jeopardizes the integrity and identity of the drugs. [See 21 CFR 225.42(b)(4)];
- failure to label all finished feeds [225.80 (a)],
- failure to maintain the building in an orderly manner in that water was leaking through a hole in the roof onto raw materials [21 CFR 225.20(b)(2)],
- failure to have a master record file for all manufactured feeds [21 CFR 225.102(a)],
- failure of production records to include a written endorsement by a responsible individual [21 CFR 225.102(b)(2)(i)], and
- failure of the master record files to contain a copy or description of the finished feed label and complete manufacturing instructions or reference thereto [21 CFR 225.102(b)(1)(iii) and (iv)].

We have also determined that your feed mill is not currently registered with the Food and Drug Administration (FDA). Under 21 CFR 207.20, you are required to register as a drug

establishment when you are using drugs that require a medicated feed mill license. The definition of a drug establishment includes manufacturers of medicated feeds under 21 CFR 207.3(a)(7). A registration form is enclosed for your use.

Based on the results of the April 15-16, 2003 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs you manufacture. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

The above is not intended as an all-inclusive list of cGMP violations. As a manufacture of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture are in compliance with the law.

You should take prompt action to correct these cGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these cGMP violations may result in regulatory and/or administration sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2).

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the cGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Joseph E. Hayes, Compliance Officer, at 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

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Enclosures:
- FDA-483
- 21 CFR Part 207
- 21 CFR Part 225
- 21 CFR Part 515.22
- Form FDA 2656-Registration of Drug Establishment
- Instruction Booklet